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10/663,198	09/15/2003	Guenter Kirschner	0259-0417P	1390

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
09/18/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/663,198	KIRSCHNER ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/15/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,15-19,21 and 23-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,15-19,21 and 23-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 7/15/09 is acknowledged.

Claims 1-11, 15-19, 21 and 23-30 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-11, 15-19, 21, 23, 25, 28, 29 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for phosphatidyl-L-serine sodium salt having a purity of "over 95%", including 100% purity. The product is disclosed as produced by *Streptomyces hachijoense* ATCC 19769 only and is then purified.

In addition, claim 23 raises the issue of new matter in the recitation of "A composition comprising a phospholipid having a titer of over 95% phosphatidyl-L- serine sodium salt having a degree of peroxidation of less than 5". It is unclear that a phospholipid having the titer recited is disclosed.

No basis or support is found in the present specification for a phosphatidyl-L-serine sodium product produced by a process wherein "the diacylglycerol of step (a) contains two fatty acids, which may be the same or different, saturated or unsaturated, having a length of between C 12 to C14" as in claim 25.

No basis or support is found in the present specification for a phosphatidyl-L-serine sodium product produced by a process wherein the phosphatide of formula II is "crude" soybean lecithin, as in claim 28.

No basis or support is found in the present specification for a phosphatidyl-L-serine sodium product with fatty acids identical to soybean lecithin produced from egg lecithin, as in claim 29.

No basis or support is found in the present specification for a phosphatidyl-L-serine sodium product produced by a process comprising a single reaction step and a single precipitation step, as in claim 30.

Therefore, this material constitutes new matter and should be deleted.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant relies on Specification on page 1, line 20 and page 8 lines 4-5 for support of claim 23. However, the specification at page 8, lines 4-5 is directed to a specific product, i.e., "1.14 kg of phosphatidylserine with a titer of over 95%, a phosphatidic acid content of less than 5% and a peroxide index of less than 5". This does not constitute the composition as claimed in new claim 23, since it does not pertain to the claimed "phospholipid having a titer of over 95% phosphatidyl-L- serine sodium salt " but rather to "phosphatidylserine" *per se*.

Applicant asserts that the product of the chemical reaction "implicitly" is the sodium salt of phosphatidyl L-serine and that it is "is very pure" due to the nature of the chemical reaction. However that cannot be equated with 100% purity as encompassed by "over 95% pure". In addition, the product by process claims provided are not directed to a specific process, but rather broadly to the use of an unidentified phospholipase D of a member of the species *Streptomyces hachijoense*.

Insertion of the limitation "over 95% pure" does not have support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of compositions wherein the sodium salt of phosphatidyl L-serine is clearly and unambiguously "over 95% pure". This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new

references cannot demonstrate possession of a concept after the fact. Thus, the insertion of phosphatidyl-L-serine sodium salt having a purity of "over 95%" is considered to be the insertion of new matter for the above reasons.

In response to the argument that at page 8, lines 4 and 27 a product having a titer of over 95% is disclosed, it is noted that this cannot be equated with "over 95% pure" as asserted. The touted products are not "phosphatidyl L-serine sodium salt ... over 95% pure".

Regarding the basis or support alleged for claims 23, 25, 28, 29 and 30 the arguments are not persuasive because the material is not present as asserted.

Therefore, this material constitutes new matter and should be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 6 appear internally inconsistent in being directed to composition comprising a product-by-process sodium salt, yet the R1 moiety is hydroxyl. No sodium is provided in the process of the product-by-process.

Claim 21 lacks clear antecedent basis in claims 1 or 2 for "phosphatidyl L-serine of claims 1 or 2", since claims 1 and 2 are directed to "a phosphatidyl L-serine sodium salt".

In addition, claim 23 raises the issue of new matter in the recitation of "A composition comprising a phospholipid having a titer of over 95% phosphatidyl-L- serine sodium salt having a degree of peroxidation of less than 5". It is unclear that a phospholipid having the titer recited is disclosed.

Claim 25 fails to find proper antecedent basis in claim 1 for wherein "the diacylglycerol of step (a) contains two fatty acids, which may be the same or different, saturated or unsaturated, having a length of between C 12 to C14".

Claim 28 is vague, indefinite and confusing in the recitation of a phosphatide of formula II that is "crude" soybean lecithin.

Claim 29 fails to find proper antecedent basis in claim 1 for producing phosphatidyl-L-serine sodium salt with fatty acids identical to soybean lecithin from egg lecithin.

Claim 30 fails to find proper antecedent basis in claim 1 for a process comprising a single reaction step and a single precipitation step.

Response to Arguments

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Applicant argues that "The claims recite a phosphatidyl-serine sodium salt of the phosphatidyl-serine formula presented in formula I".

Yet the claim reads "a phosphatidyl-L-serine sodium salt of formula (I)

R - O - PO(OH) - O - R_1 (I)

wherein R is diacylglycerol and R_1 is a hydrogen".

Applicant is reading words into the claim that are not present.

Therefore the rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-11, 15-19, and 23 are/remain rejected under 35 U.S.C. 102(e) as being anticipated by Sakai (U.S. Patent No. 6,117,853)

The claims are drawn to a phosphatidyl-L-serine sodium salt product having a fatty acid composition identical to that of soybean lecithin or egg lecithin having a degree of peroxidation less than 5 produced by a certain process.

Sakai discloses a phosphatidyl-L-serine composition which contains phosphatidyl-L-serine sodium salt compositions having the same structure as claimed and which is recognized to be useful as a food additive or a pharmaceutical for oral administration. See, e.g., Examples 1 and 5. Inasmuch as a sodium phosphate buffer is used, phosphatidyl-L-serine sodium salt is present at least to some extent.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the

conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that Sakai does not disclose a composition having a purity of 95% or more, and with a degree of peroxidation of less than 5. However, applicant fails to recognize that the 102(b) rejection is made on the composition claims wherein the amount of phosphatidyl-L-serine sodium salt in the composition is not specified. Applicant persists in equating compound claims with composition claims regarding the contents thereof. Inasmuch as the composition of Sakai contains the same critical ingredient as claimed in some amount, it can reasonably be presumed that upon mixing with other ingredients in the composition, the effect of phosphatidyl-L-serine sodium salt, will be the same, regardless of the initial degree of purity, and applicant has not shown otherwise.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' pharmaceutical, cosmetic and food compositions differ and, if so, to what extent, from the compositions discussed in the references. The amount of the compounds of interest in the composition is not a claim designated limitation. Accordingly, inasmuch as the examiner has established that the prior art compositions contain the same active ingredient as that claimed, she has reasonably demonstrated a reasonable likelihood/possibility that the compared compositions are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Applicant has not provided evidence to substantiate arguments directed towards the purity of the composition as a whole or the amount of phosphatidyl-L-serine sodium salt contained therein.

Similarly, applicant has not substantiated the arguments directed to Sakai as "non-enabling" with appropriate evidence. That the reference does not disclose a phosphatidyl-L-serine sodium salt of 95% purity or more, is not disputed. However, the compositions therein contain this material and the purity thereof cannot be readily assessed even in light of the Menon experiments. The Menon Declaration is directed to phosphatidyl-L-serine sodium salt *per se* and fails to address the material claimed in composition claims. Moreover,

In this application, Applicant has produced phosphatidyl-L-serine sodium salt by a certain process. Then applicant has placed some amount, which includes traces, into a composition. The resulting composition cannot be readily distinguished from other pharmaceutical or cosmetic compositions containing the known product phosphatidyl-L-serine sodium salt. The purity of the original product is irrelevant upon placement of some small amount of this pure product in a *gemisch* such as a cosmetic or pharmaceutical composition. Applicant has not patentably distinguished compositions containing traces of the phosphatidyl-L-serine sodium salt produced in the instant process from the compositions disclosed in Sakai.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of differences with the prior art. It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

Claims 1-11, 15-19, 21 and 23-30 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai taken with De Ferra *et al.,* Horrobin (U.S. Patent No. 5,466,841), Puricelli, Chemical Land 21 and Kurihara *et al.*(U.S. Patent No. 5,785,984).

Sakai *et al.* is discussed above. Even though the reference does not explicitly recite the sodium salt of phosphatidyl serine in the required purity, it clearly recognizes that at least the sodium salts of lysophosphatidyl serine. In addition, De Ferra discloses the conversion of calcium salts to any other salt using conventional techniques, which strongly suggests that one of ordinary skill in the art recognizes that various salts of phosphatidyl serine, including sodium

salts, were well known in the art at the time the claimed invention was made (See, e.g., col. 4, lines 30-33).

The reference differs from the claimed invention in that no cosmetics or pharmaceutical preparations containing phosphatides are disclosed. However, each of Horrobin (U.S. Patent No. 5,466,841), Puricelli, and Chemical Land 21 each discloses pharmaceutical compositions which are pharmaceuticals useful as cosmetics and/or food additives See, e.g., Horrobin, See, e.g., col. 13, line 45 et seq. and claim 4; Puricelli, pages 3-4 and Examples; and Chemical Land 21, General Description and Applications..

In addition Kurihara *et al.* disclose edible products containing soybean lecithin (See, e.g., Examples 4-5) or phosphates,(See, e.g., Examples 21, 23, 27, 29). Kurihara *et al.* also demonstrates that various forms of providing pharmaceuticals and/or cosmetics are old and well known in the art. See, e.g., col. 7-9.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or

substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the product of Sakai, if necessary, as suggested by De Ferra *et al.* for use in cosmetics and pharmaceuticals by adding suitable carriers and providing the compositions in various forms, as suggested by the teachings of Sakai, De Ferra *et al.* and Kurihara *et al.*, for the expected benefit of providing compositions which are orally administrable and that have favorable organoleptic as well as superior pharmaceutical and cosmetic properties.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant states that the claimed product could not be made by Sakai basing this conclusion on the Menon declaration. The declaration indicates that a composition containing 40% phosphatidyl serine is produced and alleges that no further purification is possible. However, from Sakai in Example 1-1 it appears that a more purified phosphatidyl-L-serine is obtained. In addition, one of ordinary skill in the art would have been motivated at the time the claimed invention was made to further purify a phosphatidyl serine product for the benefits of providing a more pure product.

While there is a difference in the enzyme source, it is noted that the reaction is Sakai is similarly a transphosphatidylation. From the Menon declaration it is not clear whether or not the same source of soybean lecithin and the same enzyme are used as are used by Sakai in the

process of the declaration. Clearly one of ordinary skill in the art would have expected different soybean lecithin sources, for example, to vary in composition.

In addition, the composition claims are directed to a composition containing undefined amounts of this product, and thus cannot be readily distinguished over the compositions disclosed by Sakai. Therefore, applicant's arguments directed to differences in purity are not relevant to the composition claims.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651